

**CORPORATE INTEGRITY AGREEMENT**  
**BETWEEN THE**  
**OFFICE OF INSPECTOR GENERAL**  
**OF THE**  
**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
**AND**  
***TOTAL PARENTERAL SERVICES OF FLORIDA, INC.***

**I.     PREAMBLE**

Total Parenteral Services of Florida, Inc., ("TPS") a pharmacy that is a mail order supplier of pre-mixed, unit dose respiratory medications, hereby enters into this Corporate Integrity Agreement ("CIA") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS") to promote compliance by its officers, directors, employees, contractors, agents, subsidiaries, third parties engaged to bill/submit reimbursement claims, and all other individuals responsible for the provision, marketing or documentation of items or services reimbursable by Federal health care programs, or in the preparation of claims, reports or other requests for reimbursement for such items or services ("Covered Persons") with the statutes, regulations and written directives of Medicare, Medicaid and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f))("Federal health care program requirements") including all legal requirements contained in any formal program directives issued by appropriate governmental agencies, e.g., the Health Care Financing Administration ("HCFA") and or their contractors. Contemporaneously with this CIA, TPS is entering into a Settlement Agreement with the United States, and this CIA is incorporated by reference into the Settlement Agreement.

**II.    TERM OF THE CIA**

The period of the compliance obligations assumed by TPS under this CIA shall be five (5) years from the effective date of this CIA (unless otherwise specified). The effective date of this CIA shall be the date on which the final signatory of this CIA executes this CIA.

Sections VII, VIII, IX, X and XI shall remain in effect until OIG has completed its review of the final annual report and any additional materials submitted by TPS pursuant to OIG's request.

### **III. CORPORATE INTEGRITY OBLIGATIONS**

TPS hereby agrees to establish a Compliance Program that includes the following elements:

#### **A. Compliance Officer and Committee.**

1. *Compliance Officer.* Within 90 days after the effective date of this CIA, TPS shall appoint an individual to serve as its Compliance Officer (such individual shall not be Merrill Davidson). The Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements. The Compliance Officer shall be a member of senior management of TPS, shall make periodic (at least quarterly) reports regarding compliance matters directly to the CEO and/or Board of Directors of TPS, and shall be authorized to report on such matters to the Board of Directors at any time. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by TPS as well as for any reporting obligations created under this CIA.

Any changes in the identity or position description of the Compliance Officer, or any actions or changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, must be reported to OIG, in writing, within 15 days of such a change.

2. *Compliance Committee.* Within 90 days of the effective date of this CIA, TPS shall appoint a Compliance Committee. The Compliance Committee shall, at a minimum, include the Compliance Officer and any other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of each major department, such as billing, clinical, human resources, audit, and operations). The Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the organization's risk areas and shall oversee monitoring of internal and external audits and investigations).

Any changes in the composition of the Compliance Committee, or any actions or changes that would affect the Compliance Committee's ability to perform the duties necessary to meet the obligations in this CIA, must be reported to OIG, in writing, within 15 days of such a change.

B. Written Standards.

1. *Code of Conduct.* Within 90 days of the effective date of this CIA, TPS shall establish a Code of Conduct. The Code of Conduct shall be distributed to all Covered Persons within 90 days of the effective date of this CIA. TPS shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. The Code of Conduct shall, at a minimum, set forth:

- a. TPS's commitment to full compliance with all Federal health care program requirements, including its commitment to prepare and submit accurate claims consistent with such requirements;
- b. TPS's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with TPS's own Policies and Procedures as implemented pursuant to section III.B (including the requirements of this CIA);
- c. the requirement that all of TPS's Covered Persons shall be expected to report to the Compliance Officer or other individual designated by the TPS suspected violations of any Federal health care program requirements or of TPS's own Policies and Procedures;
- d. the possible consequences to both TPS and Covered Persons of failure to comply with all Federal health care program requirements and with TPS's own Policies and Procedures or of failure to report such non-compliance; and
- e. the right of all individuals to use the Disclosure Program described in section III.E, and TPS's commitment to maintain confidentiality, as appropriate, and non-retaliation with respect to disclosures.

Within 90 days of the effective date of the CIA, each Covered Person shall certify, in writing, that he or she has received, read, understood, and will abide by TPS's Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within two weeks after becoming a Covered Person or within 90 days of the effective date of the CIA, whichever is later.

TPS shall annually review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such a review. Any such revised Code of Conduct shall be distributed within 30 days of finalizing such changes. Covered Persons shall certify that they have received, read, understood and will abide by the revised Code of Conduct within 30 days of the distribution of such revisions.

2. *Policies and Procedures.* Within 90 days of the effective date of this CIA, TPS shall implement written Policies and Procedures regarding the operation of TPS's compliance program and its compliance with Federal health care program requirements. At a minimum, the Policies and Procedures shall address:

- a. the subjects relating to the Code of Conduct identified in section III.B.1;
- b. business arrangements or contracts that induce the unlawful referral of Federal health care program beneficiaries, in violation of 42 U.S.C. § 1320a-7b(b) (the Anti-Kickback Statute) or 42 U.S.C. § 1395nn (the "Stark Law"); and
- c. the requirements set forth in Sections III.D and III.E.

The Policies and Procedures shall be available to the OIG upon request.

Within 90 days of the effective date of the CIA, the relevant portions of the Policies and Procedures shall be distributed to all individuals whose job functions are related to those Policies and Procedures. Appropriate and knowledgeable staff should be available to explain the Policies and Procedures.

At least annually (and more frequently if appropriate), TPS shall assess and update as necessary the Policies and Procedures. Within 30 days of the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall be

distributed to all individuals whose job functions are related to those Policies and Procedures.

C. Training and Education.

1. *General Training.* Within 90 days of the effective date of this CIA, TPS shall provide at least two hours of general training to each Covered Person. This training, at a minimum, shall explain TPS's:

- a. CIA requirements; and
- b. Compliance Program (including the Code of Conduct and the Policies and Procedures as they pertain to general compliance issues).

All training materials shall be made available to the OIG, upon request.

New Covered Persons shall receive the general training described above within 30 days of becoming a Covered Person or within 90 days after the effective date of this CIA, whichever is later. After receiving the initial training described above, each Covered Person shall receive at least one hour of general training annually.

2. *Specific Training.* Within 90 days of the effective date of this CIA, each Covered Person who is involved directly or indirectly in the delivery of patient care items or services and/or in the preparation or submission of claims for reimbursement from any Federal health care program (hereinafter referred to as "Relevant Covered Persons") shall receive at least three (3) hours of specific training in the first year of this CIA and two (2) hours thereafter in addition to the general training required above. This specific training shall include a discussion of:

- a. the submission of accurate bills for services rendered to Federal health care program beneficiaries;
- b. policies, procedures and other requirements applicable to the documentation of medical records;

- c. the personal obligation of each individual involved in the billing process to ensure that such billings are accurate;
- d. applicable reimbursement statutes, regulations, and program requirements and directives;
- e. the legal sanctions for improper billings; and
- f. examples of proper and improper billing practices.

Persons providing the training must be knowledgeable about the subject area.

Relevant Covered Persons shall receive this training within 30 days of the beginning of their employment or becoming Relevant Covered Persons or within 90 days of the effective date of this CIA, whichever is later. A TPS employee who has completed the specific training shall review a new Relevant Covered Person's work, to the extent that the work relates to the delivery of patient care items or services and/or in the preparation or submission of claims for reimbursement from any Federal health care program, until such time as the new Relevant Covered Person completes applicable training.

3. *Sales Training.* Within 90 days of the Effective Date of this CIA, each Covered Person who is involved directly or indirectly in the sales or marketing of items and services ("Sales Personnel") shall receive at least three (3) hours of training in addition to the General Training required above (the "Sales Training"). The Sales Training may be provided in a group setting and shall include a discussion of:

- a. 42 U.S.C. § 1320a-7b(b) (the "Anti-Kickback Statute") and 42 U.S.C. § 1395nn (the "Stark Law"), and the regulations and other guidance documents related to these statutes;
- b. policies, procedures and other requirements applicable to the Federal health care program requirements of medical necessity and Certificates of Medical Necessity;
- c. the personal obligation of each individual involved in the billing process to make appropriate and accurate

representations regarding coverage and billing for Items and Services;

- d. applicable Legal Requirements;
- e. the legal sanctions for improper sales or marketing strategies or arrangements; and
- f. examples of proper and improper marketing strategies or arrangements.

Individuals who newly meet the definition of Sales Personnel shall receive the Sales Training set forth above within one (1) month after becoming a Sales Personnel or within 90 days of the Effective Date of this CIA, whichever is later. If a new Sales Personnel has any responsibility for the sales or marketing of items or services prior to completing the Sales Training set forth above, a TPS employee, contractor or agent who has completed the Sales Training shall review all of such Sales Personnel's work regarding the sales and marketing of items and services, until the required training has been completed. Each Sales Personnel shall receive the Sales Training on an annual basis.

All Sales Training materials shall be made available to OIG, upon request. Persons providing the Sales Training must be knowledgeable with respect to the areas listed above.

4. *Certification.* Each individual who is required to attend training shall certify, in writing, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Officer (or his or her designee) shall retain the certifications, along with all course materials. These shall be made available to OIG, upon request.

D. Contracts for Marketing and Sales Related Services.

TPS shall create procedures reasonably designed to prevent contractual arrangements with referral sources and recipients of referrals from violating the Anti-Kickback Statute and the Stark Law, and shall implement procedures to evaluate all existing contractual relationships with contractors, vendors, and agents to the extent not

already so evaluated. At a minimum, TPS shall ensure that all new and/or renewed (*i.e.*, at renewal date) independent contractor agreements related to (1) the sales of marketing of its items or services (commission or non-commission based), or (2) with parties in a position to refer or recommend Federal health care program beneficiaries to TPS for the purchasing, leasing, or ordering of any items or services, or facility for which payment may be made in whole or in part from a Federal health care program, under which such parties are to provide marketing or sales-related services to TPS, meet the following requirements:

1. The agreement shall be in writing and signed by the parties;
2. The agreement shall specify the actual services to be provided by the independent contractor to TPS;
3. The payment under the agreement or compensation rate, which may be based on hours worked or other service-based criteria, paid to the independent contractor shall be set in advance, be consistent with fair market value in an arms length transaction, and not be determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under any Federal health care program;
4. The services performed under the agreement shall not involve the counseling or promotion of a business arrangement or other activity that violates state or federal law;
5. The contract shall include a provision that the individual independent contractor shall comply with TPS's Corporate Compliance Program which includes training related to the Anti-Kickback Statute and the Stark Law. Additionally, TPS will provide any contractor with a copy of its code of conduct and Anti-Kickback policies and procedures;
6. The individual independent contractor shall be required to certify, at the time of signing the agreement and annually thereafter, that the independent contractor:



- a. does not have a Medicare Part B provider or supplier number (*i.e.*, anyone who is a marketer cannot also be a supplier);
  - b. is an individual or entity who is not in a position to make or influence referrals or otherwise generate federal health care program business; and
  - c. is not an immediate family member or member of the household (as defined by 42 U.S.C. § 1320a-7(j)) of any individual who has a Medicare Part B provider or supplier number where that individual, or an entity owned or controlled by that individual, refers business to TPS;
7. The agreement shall require the independent contractor to notify TPS prior to a change in circumstances under which the contractor could not truthfully certify the above facts for any time period during which the contract is in effect;

E. Contracts for Commissioned and Non-Commissioned Independent Contractors

1. The agreement shall require the independent contractor to certify, at the time of signing the agreement, that the contractor shall comply with TPS's Corporate Compliance Program and with the Anti-Kickback Statute and the Stark Law; and
2. Where the commissioned independent contractor promotes items or services other than those of TPS, any discount or reduction in price of any such other item or service will not be conditioned on the purchase or lease of any items or services offered by TPS which are promoted by the commissioned independent contractor.

TPS' Compliance Officer or qualified Legal Counsel will review all of TPS' independent contractor agreements and will verify to the best of his/her knowledge and belief that all of the provisions in III.D are satisfied. TPS will report to the OIG in its annual report any independent contractor agreements that it finds do not meet the

requirement of III.D; and will report on all corrective measures taken to satisfy the requirements of III.D, including termination of the contract.

Additionally, TPS shall provide to OIG, upon request, copies of all personal services and management contracts subject to this Section III.D, and, to the extent available, all non-privileged communications related to the contracts and the actual performance of the duties under the contracts such as time sheets, service logs, and payment documentation (e.g., Form 1099s and record of checks/wire transfers).

F. Commission Sales Employees.

TPS shall institute a policy or policies reasonably designed to prevent each of its agreements with sales or marketing employees who are compensated, in whole or in part, by TPS on a basis influenced by the amount of items and services provided or the number of customers acquired by TPS (“Commission Sales Employee(s)”) from violating the Anti-Kickback Statute. At a minimum, TPS shall ensure that its relationships and agreements with Commission Sales Employees are structured to meet the following requirements:

1. Each Commission Sales Employee must be a bona fide “employee” (as that term is defined by 26 U.S.C. § 3121(d) (2) and the Internal Revenue Service’s interpretation of that provision as codified in its regulations and other interpretive sources);
2. Each Commission Sales Employee shall certify, in writing, that he or she understands and agrees that:
  - a. a failure to meet any of the requirements in this section III.E shall be grounds for termination of employment of that Commission Sales Employee;
  - b. where the Commission Sales Employee promotes items or services other than those of TPS, any discount or reduction in price of any such other item or service will not be conditioned on the purchase or lease of any Items or Services offered by TPS which are promoted by the Commission Sales Employee;

3. The sales or marketing of any Items or Services offered by TPS and marketed by any Sales Employee shall not include the direct offer, promotion, sale or lease to any Federal health care program beneficiary as specifically set forth in 42 U.S.C. § 1395m(a)(17);
4. Each Commission Sales Employee and Independent Contractor shall be required to obtain prior approval by the Compliance Officer before giving any gift to any individual or entity that is a possible referral source to TPS. The Compliance Officer shall implement and post standards for gift giving to possible referral sources to TPS;
5. Each Commission Sales Employee shall certify, in writing, that he or she:
  - a. is not a provider of services;
  - b. does not have a financial relationship with any individual or entity that has a Medicare Part B provider or supplier number where that individual or entity refers business to TPS; and
  - c. is not an immediate family member or member of the household (as defined by 42 U.S.C. § 1320a-7(j)) of any individual who has a Medicare Part B provider or supplier number where that individual or entity refers business to TPS; and
6. Each Commission Sales Employee shall be required to notify TPS prior to a change in circumstances under which the employee could not truthfully certify the above facts.

If a Commission Sales Employee fails to meet any of these standards, TPS shall notify such employee of such failure and TPS shall attempt to cure such failure within 30 days. In the event the Commission Sales Employee has not cured any such breach within the 30-day period, TPS shall terminate the employment of that Commission Sales Employee. All documents relating the failure of any Commission Sales Employee to meet any of the above standards shall be made available to the OIG upon request. TPS shall report the failure of any Commission Sales Employee to meet any of the above

standards, as well as the action taken by TPS in response to such failure, to the OIG in TPS's Annual Report.

G. Review Procedures.

1. *General Description.*

a. **Retention of Independent Review Organization.** Within 90 days of the effective date of this CIA, TPS shall retain an entity (or entities), such as an accounting, auditing or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform review engagements to assist TPS in assessing and evaluating its billing and coding practices and its compliance obligations pursuant to this CIA and the Settlement Agreement. Each Independent Review Organization retained by TPS shall have expertise in the billing, coding, reporting and other requirements of the particular section of the health care industry pertaining to this CIA and in the general requirements of the Federal health care program(s) from which TPS seeks reimbursement. Each IRO shall assess, along with TPS, whether it can perform the IRO engagements in a professionally independent fashion taking into account any other business relationships or other engagements that may exist.

b. **Types of Engagements.** The Independent Review Organization(s) shall conduct three separate engagements. The first engagement shall address TPS's independent contractors and contractor agreements, employment agreements and relationships with Commission Sales Employees (Legal Engagement). The Legal Engagement shall be conducted by an individual with appropriate knowledge to analyze the sufficiency of TPS' contracts (Legal Reviewer). The second engagement shall address TPS's billing and coding to the Federal health care programs ("Billing Engagement"). The third engagement shall address TPS's compliance with the obligations assumed under this CIA and the Settlement Agreement ("Compliance Engagement").

c. Frequency of Legal, Billing and Compliance Engagements. The Legal Engagement and Billing Engagement shall be performed annually and shall cover each of the one-year periods beginning with the effective date of this CIA. The IRO(s) shall perform all components of each annual Billing Engagement. The Compliance Engagement shall be performed by the IRO only for the first one-year period beginning with the effective date of this CIA.

d. Retention of Records. The Legal Reviewer, the IRO and TPS shall retain and make available to the OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and TPS) related to the engagements.

## *2. Legal Engagement.*

a. Legal Review. The Legal Engagement shall consist of a review of all applicable independent contractor agreements and employment agreements or relationships with Commission Sales Employees that fall within the scope of Sections III.D or III.E to evaluate whether such agreements and relationships meet the applicable requirements and standards set forth in Sections III.D and III.E (“Legal Review”).

b. Legal Review Report. The Legal Reviewer shall prepare a report of the Legal Engagement (“Legal Review Report”). In the Legal Review Report, the Legal Reviewer shall certify that the Legal Review has occurred and the Legal Review Report shall include a summary of the findings of the Legal Review. TPS shall retain all agreements and policies that have been reviewed as well as all written reports generated by the Legal Reviewer relating to the Legal Review, including the Legal Review Report.

3. *Billing Engagement.* The Billing Engagement shall be composed of two separate reviews, a “Claims Review” and a “Systems Review.” The Claims Review and corresponding Claims Review Report are discussed in detail in Appendix A to this CIA, which is incorporated by reference.

- a. Claims Review. The IRO shall perform a Claims Review to identify any overpayments through an appraisal of Paid Claims submitted by TPS to the Medicare program. The Claims Review shall be performed in accordance with the procedures set forth in Appendix A to this CIA.
- b. Claims Review Report. The IRO shall prepare a report based upon each Claims Review performed ("Claims Review Report"). The Claims Review Report shall be created in accordance with the procedures set forth in Appendix A to this CIA.
- c. Systems Review. The IRO shall review TPS's billing and coding systems and/or operations (the "Systems Review"). The Systems Review shall consist of a thorough review of the following:
  - i. TPS's billing systems and/or operations relating to claims submitted to all Federal health care programs (including, but not limited to, the operation of the billing system, safeguards to ensure proper claim submission and billing, and procedures to correct inaccurate billing); and
  - ii. TPS's coding systems and/or operations relating to claims submitted to all Federal health care programs (including, but not limited to, the process by which claims are coded, safeguards to ensure proper coding, and procedures to correct inaccurate coding).
- d. Systems Review Report. The IRO shall prepare a report based upon each Systems Review performed ("Systems Review Report"). The Systems Review Report shall include the IRO's findings and supporting rationale regarding:
  - i. the strengths and weaknesses in TPS's billing systems and/or operations;
  - ii. the strengths and weaknesses in TPS's coding systems and/or operations; and

iii. any recommendations the IRO may have to improve any of these systems, operations, and processes.

#### 4. *Compliance Engagement.*

a. Compliance Review. The IRO shall conduct a review of TPS's compliance activities ("Compliance Review"). The Compliance Review shall consist of a review of TPS's adherence to the obligations set forth in sections I through VIII of this CIA, and a review of TPS's compliance with certain provisions of the Settlement Agreement

i. CIA Obligations Review. The IRO shall assess and evaluate TPS's compliance with the obligations set forth in sections I through VIII of this CIA.

ii. Unallowable Costs Review. The IRO shall determine whether TPS has complied with its obligation not to charge to, or otherwise seek payment from, Federal or State payors for unallowable costs (as defined in the Settlement Agreement) and its obligation to identify to applicable Federal or State payors any unallowable costs included in payments previously sought from the United States, or any State Medicaid program. This unallowable cost analysis shall include, but not be limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by TPS or any of its subsidiaries, and to request, and agree, that such cost reports, cost statements, information reports or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the unallowable costs. In making this determination, the IRO may need to review cost reports and/or financial statements from the year in which of the Settlement Agreement was executed, as well as from previous years.

b. Compliance Review Report. The IRO shall prepare a report based upon the Compliance Review performed (the "Compliance Review Report"). The Compliance Review Report shall include:

- i. the IRO's findings, supporting rationale, and a summary of such findings and rationale regarding TPS's compliance with the terms of sections I through VIII of the CIA, as applicable; and
- ii. the IRO's findings and supporting rationale regarding whether TPS has complied with its obligation not to charge to, or otherwise seek payment from, Federal or State payors for unallowable costs (as defined in the Settlement Agreement) and its obligation to identify to applicable Federal or State payors any unallowable costs included in payments previously sought from such payor

5. *Validation Review.* In the event the OIG has reason to believe that:

(a) TPS's Legal, Billing or Compliance Engagement fails to conform to the requirements of this CIA; or (b) the findings or Claims Review results are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the Billing and Compliance Engagements comply with the requirements of the CIA and/or the findings or Claims Review results are inaccurate. TPS agrees to pay for the reasonable cost of any such review performed by the OIG or any of its designated agents so long as it is initiated before one year after TPS' final submission (as described in section II) is received by the OIG.

6. *Independence Certification.* Within 120 days from the effective date of this CIA, the IRO shall provide to TPS a certification or sworn affidavit that it has evaluated its professional independence with regard to the Legal, Billing and Compliance Engagements and that it has concluded that it is, in fact, independent. Such certification shall be included in TPS's Implementation Report submission

#### H. Disclosure Program.

Within 90 days after the effective date of this CIA, TPS shall establish a Disclosure Program, that must include a mechanism (e.g., a toll-free compliance



telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with TPS's policies, conduct, practices, or procedures with respect to a Federal health care program, believed by the individual to be a potential violation of criminal, civil or administrative law. TPS shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a non-retribution, non-retaliation policy, and shall include a reporting mechanism for anonymous, confidential communications. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, TPS shall conduct an internal review of the allegations set forth in such a disclosure and ensure that proper follow-up is conducted.

The Compliance Officer (or his or her designee) shall maintain a disclosure log, which shall include a record and summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews. The disclosure log shall be available to OIG, upon request.

#### I. Ineligible Persons.

1. *Definition.* For purposes of this CIA, an "Ineligible Person" shall be any individual or entity who: (a) is currently excluded, debarred or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or non-procurement programs; or (b) has been convicted of a criminal offense related to the provision of health care items or services, but has not yet been excluded, debarred or otherwise declared ineligible.

2. *Screening Requirements.* TPS shall not hire as employees or engage as contractors any Ineligible Person. To prevent hiring or contracting with any Ineligible

Person, TPS shall screen all prospective employees and prospective contractors prior to engaging their services by: (a) requiring applicants to disclose whether they are Ineligible Persons; and (b) reviewing the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at <http://epls.arnet.gov>) and the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://www.hhs.gov/oig>) (these lists will hereinafter be referred to as the "Exclusion Lists").

3. *Review and Removal Requirement.* Within 90 days of the effective date of this CIA, TPS shall review its list of current employees and contractors against the Exclusion Lists. Thereafter, TPS shall review its list of current employees and contractors against the Exclusion Lists semi-annually. In addition, TPS shall require employees and contractors to disclose immediately any debarment, exclusion or other event that makes the employee an Ineligible Person.

If TPS has notice that an employee or contractor has become an Ineligible Person, TPS shall remove such person from responsibility for, or involvement with, TPS's business operations related to the Federal health care programs and shall remove such person from any position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If TPS has notice that an employee or contractor is charged with a criminal offense related to any Federal health care program, or is proposed for exclusion during his or her employment or contract, the TPS shall take all appropriate actions to ensure that the responsibilities of that employee or contractor have not and shall not adversely affect the quality of care rendered to any beneficiary, patient or resident, or the accuracy of any claims submitted to any Federal health care program.

#### J. Notification of Government Investigation or Legal Proceedings.

Within 30 days of discovery, TPS shall notify OIG, in writing, of any ongoing investigation or legal proceeding conducted or brought by a governmental entity or its agents involving an allegation that TPS has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the

identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. TPS shall also provide written notice to OIG within 30 days of the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the proceedings, if any.

K. Reporting.

1. *Overpayments*

a. *Definition of Overpayments.* For purposes of this CIA, an “overpayment” shall mean the amount of money TPS has received in excess of the amount due and payable under any Federal health care program requirements. TPS may not subtract any underpayments for purposes of determining the amount of relevant “overpayments” for CIA reports.

b. *Reporting of Overpayments.* If, at any time, TPS identifies or learns of any overpayments, TPS shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days of identification of the overpayment and take remedial steps within 60 days of discovery (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the overpayments from recurring. Also, within 30 days of identification of the overpayment, TPS shall repay the overpayment to the appropriate payor to the extent such overpayment has been quantified. If not yet quantified, within 30 days of identification, TPS shall notify the payor of its efforts to quantify the overpayment amount along with a schedule of when such work is expected to be completed. Notification and repayment to the contractor should be done in accordance with the contractor policies, and for Medicare contractors, must include the information contained on the Overpayment Refund Form, provided as Appendix B to this CIA.

## 2. *Material Deficiencies.*

*a. Definition of Material Deficiency.* For purposes of this CIA, a “Material Deficiency” means anything that involves:

- (i) a substantial overpayment;
- (ii) a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized; or

A Material Deficiency may be the result of an isolated event or a series of occurrences.

*b. Reporting of Material Deficiencies.* If TPS determines through any means that there is a Material Deficiency, TPS shall notify OIG, in writing, within 30 days of making the determination that the Material Deficiency exists. The report to the OIG shall include the following information:

(i) If the Material Deficiency results in an overpayment, the report to the OIG shall be made at the same time as the notification to the payor required in section III.H.1, and shall include all of the information on the Overpayment Refund Form, as well as:

(A) the payor’s name, address, and contact person to whom the overpayment was sent; and

(B) the date of the check and identification number (or electronic transaction number) on which the overpayment was repaid/refunded;

(ii) a complete description of the Material Deficiency, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;

(iii) a description of TPS's actions taken to correct the Material Deficiency; and

(iv) any further steps TPS plans to take to address the Material Deficiency and prevent it from recurring.

#### **IV. NEW BUSINESS UNITS OR LOCATIONS**

In the event that, after the effective date of this CIA, TPS changes locations or purchases or establishes new business units related to the furnishing of items or services that may be reimbursed by Federal health care programs, TPS shall notify OIG of this fact as soon as possible, but no later than within 30 days of the date of change of location, purchase or establishment. This notification shall include the location of the new operation(s), phone number, fax number, Medicare provider number(s) (if any), and the corresponding contractor's name and address that has issued each Medicare provider number. All Covered Persons at such locations shall be subject to the applicable requirements in this CIA (e.g., completing certifications and undergoing training).

#### **V. IMPLEMENTATION AND ANNUAL REPORTS**

A. Implementation Report. Within 120 days after the effective date of this CIA, TPS shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA. This Implementation Report shall include:

1. the name, address, phone number, position description, and summary of other non-compliance job responsibilities of the Compliance Officer required by section III.A;
2. the names and positions of the members of the Compliance Committee required by section III.A;
3. a copy of TPS's Code of Conduct required by section III.B.1;
4. a copy of all compliance-related Policies and Procedures required by section III.B.2 and a summary of all other Policies and Procedures required by section III.B.2;

5. a copy of all training materials used for the training required by section III.C, a description of such training, including a description of the targeted audiences, length of sessions, which sessions were mandatory and for whom, percentage of attendance, and a schedule of when the training sessions were held;

6. a certification by the Compliance Officer that:

a. the Policies and Procedures required by section III.B have been developed, are being implemented, and have been distributed to all appropriate Covered Persons;

b. all Covered Persons have completed the Code of Conduct certification required by section III.B.1; and

c. all Covered Persons have completed the applicable training and executed the certification(s) required by section III.C.;

The documentation supporting this certification shall be available to OIG, upon request.

7. a description of the Disclosure Program required by section III.G;

8. the identity of the Legal Reviewer and the IRO(s), a summary/description of all engagements between TPS and the IRO, including, but not limited to, any outside financial audits, compliance program engagements, or reimbursement consulting, and the proposed start and completion dates of the first annual Legal Engagement, Billing Engagement, and Compliance Engagement;

9. a certification from the IRO regarding its professional independence from the TPS;

10. a summary of personnel actions (other than hiring) taken pursuant to section III.F.;

11. a list of all of TPS's locations (including locations and mailing addresses), the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Medicare provider identification number(s) and the contractor's name and address that issued each provider identification number;

12. to the extent not already furnished to OIG, or if modified, a description of TPS's corporate structure, including identification of any parent and sister companies, subsidiaries and their respective lines of business; and

13. the certification required by section V.C.

B. Annual Reports. TPS shall submit to OIG Annual Reports with respect to the status of, and findings regarding, TPS's compliance activities for each of the five one-year periods beginning on the effective date of the CIA. (The one-year period covered by each Annual Report shall be referred to as "the Reporting Period").

Each Annual Report shall include:

1. any change in the identity, position description, or other non-compliance job responsibilities of the Compliance Officer and any change in the membership of the Compliance Committee described in section III.A;

2. a certification by the Compliance Officer that:

a. all Covered Persons have completed any Code of Conduct certifications required by section III.B.1;

b. all Covered Persons have completed the applicable training and executed the certification(s) required by section III.C & D;

c. TPS has complied with its obligations under the Settlement Agreement: (i) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (ii) not to charge to or otherwise seek payment from Federal or State payors for unallowable costs (as defined in the

Settlement Agreement); and (iii) to identify and adjust any past charges or claims for unallowable costs; and

d. he/she has reviewed to the best of his/her knowledge and belief all independent contractor agreements and has reported any failure to meet the requirements of section III.D and all corrective measures taken to remedy the failure.

The documentation supporting this certification shall be available to OIG, upon request.

3. a summary of any significant changes or amendments to the Policies and Procedures required by section III.B and the reasons for such changes (e.g., change in contractor policy) and copies of any compliance-related Policies and Procedures;

4. a copy of all training materials used for the training required by section III.C (to the extent it has not already been provided as part of the Implementation Report), a description of such training conducted during the Reporting Period, including a description of the targeted audiences, length of sessions, which sessions were mandatory and for whom, percentage of attendance, and a schedule of when the training sessions were held;

5. a complete copy of all reports prepared pursuant to the IRO's billing, legal and compliance engagements, including a copy of the methodology used, along with a copy of the IRO's engagement letter;

6. TPS's response and corrective action plan(s) related to any issues raised by the IRO(s);

7. a revised summary/description of all engagements between TPS and the IRO, including, but not limited to, any outside financial audits, compliance program engagements, or reimbursement consulting, if different from what was submitted as part of the Implementation Report;



8. a summary of Material Deficiencies (as defined in III.J) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Material Deficiencies;
9. a report of the aggregate overpayments that have been returned to the Federal health care programs. Overpayment amounts should be broken down into the following categories: Medicare, Medicaid (report each applicable state separately) and other Federal health care programs;
10. a summary of the disclosures in the disclosure log required by section III.E that: (a) relate to Federal health care programs; or (b) allege abuse or neglect of patients;
11. a description of any personnel actions (other than hiring) taken by TPS as a result of the obligations in section III.F, and the name, title, and responsibilities of any person that falls within the ambit of section III.F.4, and the actions taken in response to the obligations set forth in that section;
12. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to section III.G. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;
13. a description of all changes to the most recently provided list (as updated) of TPS's locations (including locations and mailing addresses) as required by section V.A.10, the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Federal health care program provider identification number(s), and the contractor name and address that issued each provider identification number;
14. TPS shall require all Sales Employees to turn in quarterly reports to the Compliance Committee, which shall be made available to the OIG upon request, and which will reveal all marketing and sales literature or presentations, and the intended audiences of the marketing or sales literature or presentations; and

15. the certification required by section V.C.

The first Annual Report shall be received by the OIG no later than 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

C. Certifications. The Implementation Report and Annual Reports shall include a certification by the Compliance Officer that: (1) except as otherwise described in the applicable report, TPS is in compliance with all of the requirements of this CIA, to the best of his or her knowledge; and (2) the Compliance Officer has reviewed the Report and has made reasonable inquiry regarding its content and believes that the information is accurate and truthful.

D. Designation of Information: TPS shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552. TPS shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

## **VI. NOTIFICATIONS AND SUBMISSION OF REPORTS**

Unless otherwise stated in writing after the effective date of this CIA, all notifications and reports required under this CIA shall be submitted to the following entities:

OIG:

Civil Recoveries Branch - Compliance Unit  
Office of Counsel to the Inspector General  
Office of Inspector General  
U.S. Department of Health and Human Services  
Cohen Building, Room 5527  
330 Independence Avenue, SW  
Washington, DC 20201  
Phone 202.619.2078  
Fax 202.205.0604

TPS:

Russ Davidson  
Total Parenteral Services of Florida, Inc.  
771 Blackburn Drive  
Mobile, AL 33608  
Phone 334.607.7152  
Fax 334.607.0771

Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail, hand delivery or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt.

## **VII. OIG INSPECTION, AUDIT AND REVIEW RIGHTS**

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of TPS's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of TPS's locations for the purpose of verifying and evaluating: (a) TPS's compliance with the terms of this CIA; and (b) TPS's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by TPS to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of TPS's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. TPS agrees to assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. TPS's employees may elect to be interviewed with or without a representative of TPS present.

## **VIII. DOCUMENT AND RECORD RETENTION**

TPS shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this CIA, for six (6) years (or longer if otherwise required by law).

## **IX. DISCLOSURES**

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, the OIG shall make a reasonable effort to notify TPS prior to any release by OIG of information submitted by TPS pursuant to its obligations under this CIA and identified upon submission by TPS as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, TPS shall have the rights set forth at 45 C.F.R. § 5.65(d). TPS shall refrain from identifying any information as exempt from release if that information does not meet the criteria for exemption from disclosure under FOIA.

## **X. BREACH AND DEFAULT PROVISIONS**

TPS is expected to fully and timely comply with all of its CIA obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, TPS and OIG hereby agree that failure to comply with certain obligations set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day TPS fails to have in place any of the obligations described in section III:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. a written Code of Conduct;
- d. written Policies and Procedures;
- e. a requirement that Covered Persons be trained; and
- f. a Disclosure Program.

2. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day TPS fails to retain an IRO, as required in section III.F.

3. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day TPS fails to meet any of the deadlines for the submission of the Implementation Report or the Annual Reports to OIG.

4. A Stipulated Penalty of \$2,000 (which shall begin to accrue on the date the failure to comply began) for each day TPS employs or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with, TPS's business operations related to the Federal health care programs; or (ii) is in a position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds (the Stipulated Penalty described in this paragraph shall not be demanded for any time period during which TPS can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.F) as to the status of the person).

5. A Stipulated Penalty of \$1,500 for each day TPS fails to grant access to the information or documentation as required in section VII of this CIA. (This Stipulated Penalty shall begin to accrue on the date TPS fails to grant access.)

6. A Stipulated Penalty of \$1,000 for each day TPS fails to comply fully and adequately with any obligation of this CIA. In its notice to TPS, OIG shall state the specific grounds for its determination that TPS has failed to comply fully and adequately with the CIA obligation(s) at issue and steps the TPS must take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after the date that OIG provides notice to TPS of the failure to comply.) A Stipulated Penalty as described in this paragraph shall not be demanded for any violation for which the OIG has sought a Stipulated Penalty under paragraphs 1-5 of this section.

B. Timely Written Requests for Extensions. TPS may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report

shall not begin to accrue until one day after TPS fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after TPS receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

### C. Payment of Stipulated Penalties.

1. *Demand Letter.* Upon a finding that TPS has failed to comply with any of the obligations described in section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify TPS of: (a) TPS's failure to comply; and (b) the OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is hereinafter referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 10 days of the receipt of the Demand Letter, TPS shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) request a hearing before an HHS administrative law judge ("ALJ") to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in section X.E. In the event TPS elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until TPS cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under section X.D.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by certified or cashier's check, payable to: "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in section VI.

4. *Independence from Material Breach Determination.* Except as set forth in section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that TPS has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in section X.D, below.

D. Exclusion for Material Breach of this CIA

1. *Definition of Material Breach.* A material breach of this CIA means:

- a. a failure by TPS to report a material deficiency, take corrective action and make the appropriate refunds, as required in section III.H;
- b. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in section X.A;
- c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with section X.C; or
- d. a failure to retain and use an Independent Review Organization in accordance with section III.D.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by TPS constitutes an independent basis for TPS's exclusion from participation in the Federal health care programs. Upon a determination by OIG that TPS has materially breached this CIA and that exclusion should be imposed, OIG shall notify TPS of: (a) TPS's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

3. *Opportunity to Cure.* TPS shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

- a. TPS is in compliance with the obligations of the CIA cited by the OIG as being the basis for the material breach;
- b. the alleged material breach has been cured; or
- c. the alleged material breach cannot be cured within the 30-day period, but that: (i) TPS has begun to take action to cure the material breach; (ii) TPS is pursuing such action with due diligence; and (iii)

TPS has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If at the conclusion of the 30-day period, TPS fails to satisfy the requirements of section X.D.3, OIG may exclude TPS from participation in the Federal health care programs. OIG will notify TPS in writing of its determination to exclude TPS (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in section X.E, below, the exclusion shall go into effect 30 days after the date of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and non-procurement programs. Reinstatement to program participation is not automatic. If at the end of the period of exclusion, TPS wishes to apply for reinstatement, TPS must submit a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

#### E. Dispute Resolution

1. *Review Rights.* Upon OIG's delivery to TPS of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, TPS shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board ("DAB"), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days of the receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days of receipt of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether TPS was in full and timely compliance with the obligations of this CIA for which the OIG demands payment; and (b) the period of noncompliance. TPS shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and



orders TPS to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless TPS requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be:

- a. whether TPS was in material breach of this CIA;
- b. whether such breach was continuing on the date of the Exclusion Letter; and
- c. whether the alleged material breach could not have been cured within the 30 day period, but that:
  - (i) TPS had begun to take action to cure the material breach within that period;
  - (ii) TPS has pursued and is pursuing such action with due diligence; and
  - (iii) TPS provided to OIG within that period a reasonable timetable for curing the material breach and TPS has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for the TPS, only after a DAB decision in favor of OIG. TPS's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude TPS upon the issuance of an ALJ's decision in favor of the OIG. If the ALJ sustains the determination of the OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that TPS may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. TPS agrees to waive

its/his/her right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB.

## **XI. EFFECTIVE AND BINDING AGREEMENT**

Consistent with the provisions in the Settlement Agreement pursuant to which this CIA is entered, and into which this CIA is incorporated, TPS and OIG agree as follows:

A. This CIA shall be binding on the successors, assigns, and transferees of TPS;

B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;

C. Any modifications to this CIA shall be made with the prior written consent of the parties to this CIA;

D. OIG may agree to a suspension of TPS's obligations under the CIA in the event of TPS's cessation of participation in Federal health care programs. If TPS withdraws from participation in Federal health care programs and is relieved from its CIA obligations by the OIG, TPS agrees to notify OIG 30 days in advance of TPS' intent to reapply as a participating provider or supplier with the Federal health care programs. Upon receipt of such notification, OIG will evaluate whether the CIA should be reactivated or modified.

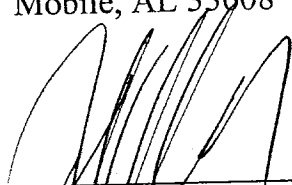
E. The undersigned TPS signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA.

ON BEHALF OF TPS



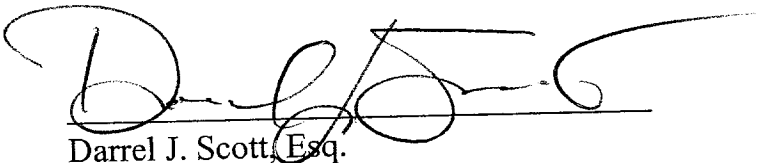
Merrill G. Davidson, President  
Total Parenteral Services of Florida, Inc.,  
771 Blackburn Drive  
Mobile, AL 33608

8/13/07  
DATE



Jeffrey S. Baird, Esq.  
Brown & Fortunato, P.C.  
906 S. Fillmore  
Amarillo, TX 79105

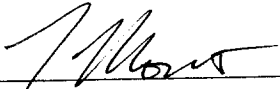
8/13/07  
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Darrel J. Scott, Esq.  
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906 S. Fillmore  
Amarillo, TX 79105

8/13/07  
DATE

**ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL  
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES**



LEWIS MORRIS

Assistant Inspector General for Legal Affairs

Office of Inspector General

U. S. Department of Health and Human Services

8/27/01  
DATE